GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA

UNSTARRED QUESTION NO:5663
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INJECTABLE CONTRACEPTIVES
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Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether clinical studies on Cyclofem, a monthly injectable contraceptive and NET-EN, a two-monthly injectable contraceptive have been carried out by the Indian Council of Medical Research;

(b) if so, the details thereof alongwith the outcome of such clinical studies;

(c) whether the Government proposes to introduce such contraceptives in the National Family Planning Programme; and

(d) if so, the details thereof?

Answer

MINISTER OF THE STATE IN THE MINISTRY OF HEALTH & FAMILY WELFARE (SMT. PANABAKA LAKSHMI)

(a): Yes, Sir.

(b): The details of the clinical studies is placed at Annexure I & II.

(c) & (d): There is no immediate decision to introduce the injectables in the National Family Welfare Program till the completed studies are evaluated.

Annexure-I

CYCLOFEM

ICMR has conducted a study on monthly injectable contraceptive, Cyclofem through its network of Human Reproduction Research Centres (HRRCs). A total of 63,754 women attended family planning clinics at 15 HRRCs of the Council were given a balanced presentation of all the contraceptive methods available in the national programme including Cyclofem (Cafeteria approach). Out of these 26,856 (42.3%) accepted Tubectomy, 116 (0.2%) couples opted for the Vasectomy, 25% accepted condoms, 15.8% accepted IUD, 14.7% accepted Oral pills and monthly injectable Cyclofem was opted by 1330 (2.1%) of total family planning seekers.

A total of 1330 women have been enrolled in the study and observed for 11518 women months of use. Mean age of acceptors is 26.0+4.1 years and mean parity of 18+1.0. Mean weight and height of acceptors is recorded as 48.2+10.9 kgs and 152.3+17.7 cms respectively. 87% of the acceptors are literate and 17.8% are employed.

539 women have used 12 injections. The continuation rates at 6, 9 and 12 months are 79.2, 73.9 and 70.3 per 100 users respectively. Majority of the discontinuations were due to menstrual irregularities 9.2 per 100 users at one year, (discontinuations due to ammenorrhoea was 2.2, 2.4 and 2.7 at 6. 9 and 12 months, discontinuation due to heavy and prolonged bleeding were 1.9, 2.1 and 2.7). Infrequent and reduced bleeding did not result in women discontinuing the method. Discontinuations due to personnel reasons were 4.7, 7.0 and 8.4 at 6, 9 and 12 months of use.

No method failure has been reported in this study. Discontinuation rate due to other medical reasons like nausea, vomitings, high Blood Pressure Rashes and itching, Weight gain and Breast tenderness were 2.2, 3.5 and 3.8 at 6,9 and 12 months.

116 women discontinued from the study due to personal reasons like transfer to other city (56), husband separated (18), objection from family members (16) and illness of the husband (12) were the major personal reasons for discontinuations.

The study has just completed and the final reports have been received in the Health Ministry for evaluation.

Annexure-II

NET-EN

Summary of the Councils trials with Net Oen

The Indian Council of Medical Research has been carrying out studies with Injectable Contraceptive Northisterone Oenanthate since early 80s in different doses and in combination with Oestogen. A brief write up on the studies carried out by the Council's are as follows:

1981-1983 : Comparative evaluation of contraceptive efficacy of norethisterone oenanthate (200mg) injectable contraceptive given every two or three monthly. (published in journal of contraception December 1984, vol. 30, No. 6)

Comparatively evaluation of Contraceptive efficacy of Northisterone Oenanthate 200 mg injection given every 2 or 3 monthly was done in a study carried out in 1981 in 2388 women which were observed for 24 months, 1181 women in 60 Â± 5 days group and 1207 in 90 Â± 5 days group. A results of the study indicated that NET OEN 200mg given every 2 months Â± 5 days provides adequate contraceptive protection. The higher method failures were reported with 90 Â± 5 days regimen which were mainly in the 3rd month of giving the injection suggesting reduced contraceptive efficacy during the 3rd month. Women weighing less than 40kg. were at a higher risk of involuntary pregnancy.

1983-84 : Phase II randomized clinical trial with Norethisterone Oenanthate 50mg alone and in combination with 5 mg or 2-5 mg of either estradiol valerate or cypionate as a monthly injectable contraceptive. (published in journal of Contraception October 1985, Vol. 32, No. 4)

A randomized clinical trial with Northisterone Oenanthate 50mg alone and in combination with either 5 or 2.5mg of either Oestradiol Valerate or Cypionate as a Monthly Contraceptive was evaluated. A total of 364 women were observed for 1686 women months of use. Analysis of the bleeding pattern data indicated that NET OEN 50mg. when given alone gave rise to delayed cycles and/or amenorrhoea. However, the addition of estrogen esters in a dose of either 2.5 or 5mg provided significantly better bleeding patterns. Of the different treatment schedules investigated, the combination of NET OEN 50mg. with E2 Val. 5mg. provided more consistent and better cycle control.

1984-1987 : A multicentre phase-III comparative study of two hormonal contraceptive preparations Net-Oen (50mg) + E2 valerate (5mg) given every month and Net-Oen (200mg) given every 2 months as intramuscular injection − A report of 12 month study. (published in journal of Contraception August 1990, Vol. 42, No. 2)

In a Multicentre Phase-III comparatively study in which NET OEN 200mg. given every 2 months was compared with NET OEN 50mg in combination with Oestradiol Valerate given every month were compared for efficacy ,side effects, acceptability and side effects. A total of 849 subjects were observed for 7817 women months of use. The results of the study indicated that women using monthly Injectable Contraceptive had better control of the menstrual cycle as compared to the 2 monthly regimen but the discontinuation were similar in both the groups.

1984-86 : Return of fertility following discontinuation of an Injectable Contraceptive − Norethisterone Oenanthate (Net-En) 200mg dose. (published in journal of Contraception December 1986, Vol. 34, No. 6)

The return of fertility following discontinuation of Net-En 200mg injectable contraceptive was studied in women who have used Net-En for a period of 6 months or more for planning pregnancy. 69 women who discontinued the method for planning pregnancy were enrolled in the study. Former users of Copper T 200 were enrolled as a control group. Another 161 women who had discontinued Net-En due to other reasons like Amennohoroea, excessive bleeding are personal reasons were also studied for return of fertility after ensuring that they were not using any other method of contraception and were exposed to the risk of pregnancy. The subjects were followed for a period of 1 year. The cumulative conception rates at the end of 1 year showed that future return of fertility in Net-En users does not appear to be adversely affected. In subjects who discontinued Net-En due to Amenohorrea, the return of fertility was predictably slower and less. The return of fertility in subjects who discontinued for other reasons e.g. excessive bleeding and other personal reasons was similar to Ex Net-En and Copper T users.

1984-88 : Programme introduction study with Injectable Contraceptive Net-Oen 200mg in Postpartum centres B&C type and Primary Health Centres attached to Medical Colleges under ROME scheme. 1983-88

Based on the results of the studies carried out by the Council which showed that NET OEN 200mg. given 2 monthly is a good contraceptive option for women desiring spacing of children. The Council from 1983 to 1988 initiated a pre-programme introductive study at Urban Post partum centre B&C type and primary health centres attached to Medical Colleges under ROME scheme. The study was initiated with the objectives of identifying the acceptability, logistic and supplies, training needs, and follow up needs and mechanisms. A total of 2449 women were observed for 11691 women months of use at 42 urban post partum centres and

531 women observed for 3180 women months of use at primary health centres selected by 11 Medical Colleges. The method failure rate was observed to be 2.1 per 100 users at post-partum centres and 1.7 per 100 users at primary health centres. Detection of pregnancy was mainly on clinical judgement and not by the pregnancy test and all such cases were recommended to undergo Medical Termination of pregnancy (MTP). Majority of the discontinuations as expected were due to menstrual irregularities; 41.2 per 100 users at post partum centres and 34.6 per 100 users at primary health centres. Continuation rates at the end of 1 year were 22.9 per 100 users at post partum centres and 29.3 per 100 users at primary health centres. The rates observed in this study were much less than those observed in clinical trials conducted at the medical colleges. The possible reasons could be that the participating centres were not familiar with this new technology and the importance of motivation and counseling skills were not available and were not taken in the right perspective. Continuation rates were better at primary health centres; this could be because of the fact that the ANMs have better rapport with the woman and thus have more frequent contacts. Percent loss to follow up was high 24.1 at post partum centres and 15.1 at primary health centres. The study concluded that Net-Oen could be made available under medical supervision only at those centres such as urban family welfare centres where adequate facilities for screening, counseling and follow up are available.

Study at NIRRH, Mumbai (a permanent institute of ICMR) 2002-2007

NIRRH initiated a multicentre study on 2 monthly injectable contraceptive (Norethisterone Enanthate) after enrolling 1209 women across India. The approved duration of total study period was 4 years and extended by one year later. The objectives were to assess user acceptability and continuation rates of this injection, to study side effects and also women's views and attitudes towards injectable contraceptives. The major emphasis of this study was on counseling by skilled councilors and quality services to the users. The results are very reassuring. The observations based on 17268 months of injection use show cumulative continuation rates at the end of 12, 18 and 24 months as 65%, 53.6% and 48.3% respectively. It was interesting to note that 39% of women requested to provide them injections beyond study period of 2 years. Over 79% women were satisfied with the method. About 89% said that the injectable should be available in our national programme and also 79% of them would recommend this method to their friends and relatives. The method was acceptable by the majority of women and was found very effective, the cumulative method failure rate was 0.3% at the end of one year.

There was no adverse effect on general or reproductive health necessitating hospitalization. About 91% of women conceived within 12 months and majority (52%) within 6 months after the discontinuation of injection was over.

The study is now nearing completion.